

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : Group Art Unit: 3737
Harvey Ellis Cline, et al. : Examiner: John Fernando Ramirez
Serial No. 10/617,543 :
Filed: July 10, 2003 : Response to Paper No.: 20060802
For: SYSTEM AND METHOD FOR THE DETECTION OF BRAIN IRON USING MAGNETIC
RESONANCE IMAGING

Mail Stop Appeal Brief – Patents

Honorable Assistant Commissioner of Patents and Trademarks,
Washington, DC 20231

APPEAL BRIEF PURSUANT TO 37 C.F.R. §§ 41.31 AND 41.37

This Appeal Brief is being filed in furtherance to the Notice of Appeal sent by facsimile and received by the Patent Office on May 22, 2006. This Appeal Brief is further in response to the Notice of Panel Decision from Pre-Appeal Brief Review mailed August 4, 2006 and the Notice of Non-Compliant Appeal Brief mailed June 21, 2007. In response to the Non-Compliant Appeal Brief notice, sections 9. Appendix of Evidence, and 10. Appendix of Related Proceedings has been added.

The Commissioner is authorized to charge the requisite fee of \$500.00, and any additional fees that may be necessary to advance prosecution of the present application, to Account No. 07-0868.

1. REAL PARTY IN INTEREST

The real party in interest is General Electric Company, the Assignee of the above-referenced application by virtue of the Assignment to General Electric Company by Harvey Cline, Ronald Watkins and John Schenck, recorded at reel 014823, frame 0948, and dated July 7, 2004. Accordingly, General Electric Company will be directly affected by the Board's decision in the pending appeal.

2. RELATED APPEALS AND INTERFERENCES

The Appellants are unaware of any other appeals or interferences related to this Appeal. The undersigned is the Appellants' legal representative in this Appeal.

3. STATUS OF CLAIMS

Claims 1-15 are currently pending, are currently under final rejection and, thus are the subject of this Appeal.

4. STATUS OF AMENDMENTS

As no amendments have been presented subsequent to the final rejection, there are no outstanding amendments to be considered by the Board.

5. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention relates generally to the field of magnetic resonance imaging (MRI). See Application, page 1, paragraph [0001]. More particularly, the invention relates to the field of image processing using MRI and detection of brain iron. See *id.* at page 1, paragraph [0001]. The Application contains four independent claims, namely, claims 1 and 9, all of which are the subject of this Appeal. The subject matter of these claims is summarized below.

With regard to the aspect of the invention set forth in independent claim 1, discussions of the recited features of claim 1 can be found at least in the locations with the specification and drawings cited below. By way of example, an embodiment in accordance with the present invention relates to a method for detecting iron in the brain using magnetic resonance imaging (MRI). See *e.g. id.* at page 7, paragraph [0021] through page 8-9, paragraph [0024] and Figure 1. The method comprises generating a substantially high magnetic field strength within the MRI system. The method also comprises acquiring magnetic resonance (MR) images at the substantially high magnetic field strength by a pulse sequence (e.g. 121) adapted to create a magnetic field map of the brain for use in enhancing brain iron deposits. See *e.g. id.* at page 8, paragraph [0024]. Further, the method comprises characterizing regions of interest using the

magnetic field maps to detect statistically relevant quantities of brain iron deposits to indicate a given disease. *See e.g. id.* at page 8, paragraph [0024].

With regard to the aspect of the invention set forth in independent claim 9, discussions of the recited features of claim 9 can be found at least in the locations within the specification and drawings cited below. By way of example, an embodiment in accordance with the present invention relates to a system for detecting iron using magnetic resonance imaging (MRI). *See e.g. id.* at page 4, paragraph [0014] through page 6, paragraph [0018] and Figure 1. The system comprises a magnetic resonance imaging device (e.g. Figure 1) having a substantially high magnetic field strength and the device being adapted for acquiring magnetic resonance (MR) images at the substantially high magnetic field strength by a pulse sequence adapted to create a magnetic field map of the brain for use in enhancing brain iron deposits. *See e.g. id.* at page 7, paragraph [0021] through page 8-9, paragraph [0024]. The system further comprises an image processor (e.g. 106) coupled to the imaging device and adapted for characterizing regions of interest using the magnetic field map to detect iron deposits for use in at least one of diagnosis, prognosis, and prediction of progression of iron-dependent diseases. *See e.g. id.* at page 7, paragraph [0021] through page 8-9, paragraph [0024].

A benefit of the invention, as recited in these claims, is the ability to detect and characterize statistically relevant quantities of brain iron deposits to indicate a given disease. *See id.*, at page 8, paragraph [0024] through page 10, paragraph [0029].

6. GROUND OF REJECTION TO BE REVIEWED ON APPEAL

First Ground of Rejection for Review on Appeal

The Appellants respectfully urge the Board to review and reverse the Examiner's first ground of rejection in which the Examiner rejected claims 1-3, 6-12 and 13 under 35 U.S.C. §103(a) as being rendered obvious by the US Patent No. 5,322,682 to Bartzokis et al ("the Bartzokis reference") in view of US Patent No. 5,603,322 to Jesmanowicz et al. ("the '322 Jesmanowicz reference").

Second Ground of Rejection for Review on Appeal

The Appellants respectfully urge the Board to review and reverse the Examiner's first ground of rejection in which the Examiner rejected claims 4, 5, 14 and 15 under 35 U.S.C. §103(a) as being rendered obvious by the Bartzokis reference in view of the '322 Jesmanowicz reference and further in view of US Patent No. 6,294,972 to Jesmanowicz et al. ("the '972 Jesmanowicz reference").

7. ARGUMENT

As discussed in detail below, the Examiner has improperly rejected the pending claims. Moreover, the Examiner has misapplied long-standing and binding legal precedents and principles in rejecting the claims under 35 U.S.C § 103(a). Accordingly, the Appellants respectfully request full and favorable consideration by the Board, as the Appellants strongly believe that claims 1-15 are currently in condition for allowance.

A. Ground of Rejection No. 1:

The Appellants respectfully urge the Board to review and reverse the Examiner's first ground of rejection in which the Examiner rejected claims 1-3, 6-12 and 13 under 35 U.S.C. §103(a) as being rendered obvious by the Bartzokis reference in view of the '322 Jesmanowicz reference. The Appellants respectfully traverse this rejection.

1. Legal Standard

The burden of establishing a *prima facie* case of obviousness falls on the Examiner. *Ex parte Wolters and Kuypers*, 214 U.S.P.Q. 735 (B.P.A.I. 1979). Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention absent some teaching or suggestion supporting the combination. *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572,1577, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984). Accordingly, to establish a *prima facie* case, the Examiner must not only show that the combination includes all of the claimed elements, but also a convincing line of reason as to why one of ordinary skill in the art would have found the claimed invention to have been obvious in light of the teachings of the references. *Ex parte Clapp*, 227 U.S.P.Q. 972 (B.P.A.I. 1985). When prior art references require a selected combination to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gained from the invention itself, i.e., something in the prior art as a whole must suggest the desirability, and thus the obviousness, of making the combination. *Uniroyal Inc. v. Rudkin-Wiley Corp.*, 837 F. 2d 1044, 5 U.S.P.Q. 2d 1434 (Fed. Cir. 1988).

2. The Examiner's rejection of claims 103, 6-12 and 13 is improper because the rejection fails to establish a *prima facie* case of obviousness.

Independent claim 1 recites:

1. A method for detecting iron in the brain using magnetic resonance imaging (MRI) comprising:

generating a substantially high magnetic field strength within the MRI system;

acquiring magnetic resonance (MR) images at the substantially high magnetic field strength by a pulse sequence adapted to create a magnetic field map of the brain for use in enhancing brain iron deposits; and,

characterizing regions of interest using the magnetic field maps to detect statistically relevant quantities of brain iron deposits to indicate a given disease.

Independent claim 9 recites:

9. A system for detecting iron using magnetic resonance imaging (MRI) comprising:

a magnetic resonance imaging device having a substantially high magnetic field strength and the device being adapted for acquiring magnetic resonance (MR) images at the substantially high magnetic field strength by a pulse sequence adapted to create a magnetic field map of the brain for use in enhancing brain iron deposits; and,

an image processor coupled to the imaging device and adapted for characterizing regions of interest using the magnetic field map to detect iron deposits for use in at least one of diagnosis, prognosis, and prediction of progression of iron-dependent diseases.

- a. The Bartzokis and '322 Jesmanowicz references alone or in combination fail to show or disclose a magnetic field map for use in characterizing regions of interest

With regard to independent claims 1 and 9, the Appellants respectfully note that the deficiencies of the Bartzokis and '322 Jesmanowicz references noted above with regard to independent claims 1 and 9 pertains to the absence of any disclosure of a *magnetic field map*. In fact, the Examiner has not presented any evidence that discloses or suggest that the Bartzokis or '322 Jesmanowicz systems or methods employ a "magnetic field map" as recited in claims 1 and 9. For at least this reason, the Appellants respectfully suggest that the Board overturn the Examiner's rejections of claims 1 and 9, as well as claims that depend therefrom.

- b. The Bartzokis and '322 Jesmanowicz references alone or in combination fail to show or disclose acquiring magnetic resonance (MR) images at the substantially high magnetic field strength by a pulse sequence adapted to create a magnetic field map of the brain for use in enhancing brain iron deposits

Specifically, the Bartzokis reference does not teach or suggest "acquiring MR images at a

substantially high magnetic field strength by a pulse sequence adapted to create a magnetic field map of the brain for use in enhancing brain iron deposits. By contrast, the Bartzokis reference teaches taking MR images at two different field strengths and thus multiple imaging sessions. The Bartzokis method requires the image information from both the multiple imaging sessions in order to obtain iron information. Indeed, Appellants respectfully submit that the Bartzokis reference teaches away from the claimed invention in that the Bartzokis reference teaches a method requiring acquiring information at two different field strengths (and therefore multiple imaging sessions) to obtain iron information. Furthermore, the '322 Jesmanowicz reference does not teach or suggest does not disclose acquiring MR images at the substantially high magnetic field strength by a pulse sequence adapted to create a magnetic field map of the brain, but merely discloses imaging the brain. For at least this additional reason, the Appellants respectfully request that the Board overturn the Examiner's rejections and allow claims 1 and 9, and claims depending therefrom.

c. The Examiner has provided no reasonable basis for modifying or combining the Bartzokis system and method with the '322 Jesmanowicz reference

Furthermore, there is no suggestion or motivation in the Bartzokis reference that the modification of combining the system of the '322 Jesmanowicz reference would be desirable. Firstly, as noted above, the Bartzokis reference is generally directed to obtaining MR image data at two different magnetic field strengths. The Appellants have noted above that the Bartzokis reference does not disclose or show acquiring MR images at a substantially high magnetic field strength by a pulse sequence adapted to create magnetic field map of the brain. The '322 Jesmanowicz reference merely discloses imaging the brain but does not disclose acquiring MR images at a substantially high magnetic field strength nor does it show or disclose a magnetic field map and further there is no disclosure or suggestion of enhancing brain iron. The Examiner's comments with regard to the proposed combination, the Examiner's rejections are based not on explicit disclosures within the cited references but merely on the Examiner's unsupported opinion of the desirability to provide a better method for iron detection. However, because there has been no showing by the Examiner that the above-recited claim features are present or desirable in the Bartzokis and '322 Jesmanowicz references, the modifications suggested by the Examiner are hardly obvious and, instead, strongly suggest the Examiner has relied on impermissible hindsight in reviewing the prior art. Accordingly, no *prima facie* case of obviousness exists with regard to claims 1 and 9. As such, the Appellants respectfully request that the Board direct the Examiner to allow claims 1 and 9 and the claims that depend therefrom.

B. Ground of Rejection No. 2

The Appellants respectfully urge the Board to review and reverse the Examiner's second ground of rejection in which the Examiner rejected claims 4, 5, 14 and 15 under 35 U.S.C. §103(a) as being rendered obvious by the Bartzokis reference in view of the '322 Jesmanowicz reference and further in view of the '972 Jesmanowicz reference. The Appellants respectfully traverse this rejection.

Each of the foregoing rejected claims depend from one of independent claims 1 or 9 discussed above. Moreover, each of the Examiner's rejections is founded upon the Bartzokis reference, which is also discussed above. With this in mind, the Appellants respectfully assert that the '322 and '972 Jesmanowicz references employed in conjunction with the Bartzokis references, does not obviate the deficiencies of the Bartzokis reference, as discussed in the foregoing remarks regarding the Examiner's rejections of claims 1 and 9. Accordingly, the Appellants respectfully assert that the instant claims are not only patentable for their respective dependencies on allowable base claims, but also by virtue of the additional features recited therein.

In light of the foregoing remarks, the Appellants respectfully request that the Board withdraw the obviousness rejections in relation to claims 1-15. Additionally, the Appellants respectfully request that the Board direct the Examiner to allow the instant claims.

Conclusion

The Appellants respectfully submit that all pending claims are in condition for allowance. However, if the Examiner or Board wishes to resolve any other issues by way of a telephone conference, the Examiner or Board is kindly invited to contact the undersigned attorney at the telephone number indicated below.

Respectfully submitted,

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September 4, 2006

Appl. S.N. 10/617,543

GE Docket 124387

Appeal Dated Sept. 4, 2006, Corrected Appeal dated July 9, 2007

Reply to Office Action of Aug. 4, 2006 and

Notice of Non-Compliant Appeal Brief Dated June 21, 2007

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8. APPENDIX OF CLAIMS ON APPEAL

Listing of Claims:

1. A method for detecting iron in the brain using magnetic resonance imaging (MRI) comprising:
 - generating a substantially high magnetic field strength within the MRI system;
 - acquiring magnetic resonance (MR) images at the substantially high magnetic field strength by a pulse sequence adapted to create a magnetic field map of the brain for use in enhancing brain iron deposits; and,
 - characterizing regions of interest using the magnetic field maps to detect statistically relevant quantities of brain iron deposits to indicate a given disease.
2. The method of claim 1 wherein the selected pulse sequence is a dual gradient echo pulse sequence and the acquiring step is performed for two different echo times.
3. The method of claim 1 wherein the acquiring step generates a three dimensional phase image of the brain.
4. The method of claim 3 wherein the magnetic field map of the brain is created by fitting a spherical harmonic series to the three dimensional phase image of the brain.
5. The method of claim 4 further comprises subtracting the spherical harmonic series from the magnetic field map to provide a measure of local variation in the magnetic field in the brain.
6. The method of claim 1 wherein the brain iron deposits are indicative of diseases comprising Alzheimer's disease, Parkinson's disease, Huntington's disease, Hallervorden Spatz disease, other neurodegenerative diseases and atherosclerotic diseases.
7. The method of claim 1 wherein the substantially high magnetic field strength is about 1.5 Tesla (1.5 T) or greater.
8. The method of claim 1 further comprising repeating the acquiring and characterizing steps in at least one successive examination of a given subject for at least one of measuring progression of the disease and measuring response to therapy.

9. A system for detecting iron using magnetic resonance imaging (MRI) comprising:

a magnetic resonance imaging device having a substantially high magnetic field strength and the device being adapted for acquiring magnetic resonance (MR) images at the substantially high magnetic field strength by a pulse sequence adapted to create a magnetic field map of the brain for use in enhancing brain iron deposits; and,

an image processor coupled to the imaging device and adapted for characterizing regions of interest using the magnetic field map to detect iron deposits for use in at least one of diagnosis, prognosis, and prediction of progression of iron-dependent diseases.

10. The system of claim 9 wherein the substantially high magnetic field strength is about 1.5 Tesla (1.5 T) and greater.

11. The system of claim 9 wherein the iron-dependent diseases comprise Alzheimer's Disease, Parkinson's Disease, Huntington's Disease, Hallervorden Spatz disease, other neurodegenerative diseases, liver diseases and atherosclerotic diseases.

12. The system of claim 9 wherein the selected pulse sequence is a dual gradient echo pulse sequence and the acquiring step is performed for two different echo times.

13. The system of claim 9 wherein the MR images create a three dimensional phase image of the brain.

14. The system of claim 13 wherein the magnetic field map of the brain is created by fitting a spherical harmonic series to the three dimensional phase image of the brain.

15. The system of claim 14 further comprises subtracting the spherical harmonic series from the magnetic field map to provide a measure of local variation in the magnetic field in the brain.

9. **APPENDIX OF EVIDENCE**

None.

10. **APPENDIX OF RELATED PROCEEDINGS**

None.